

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed September 19, 2006. Currently, claims 46-60 remain pending of which claims 46-60 have been rejected. In this amendment, claims 46, 54, and 60 have been amended. Favorable consideration of the following remarks is respectfully requested.

Claim Objections

Claim 46 was objected to because of the following informalities: in line 9, “inner sheath” should be changed to “inner shaft”, the phrase “rotatable along a line that is parallel to a longitudinal axis of the outer sheath” is unclear and it is suggested to change it to rotatable about an axis parallel or coincident with the axis of the sheath. Accordingly, Applicant has amended claim 46 to recite “inner shaft” and “rotatable about an axis parallel or coincident with the axis of the sheath”. Applicant thanks Examiner for the suggestions and respectfully requests withdrawal of the objection.

Claim rejections – 35 USC § 102

Claims 46-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Olson et al. (USPN 5,906,619). After careful review, Applicant must respectfully traverse the rejection.

The Office Action recites, “Olson discloses a device including an outer sheath 32, an inner sheath 34 having runners 42 at the distal end for holding a distal protection device (stent), a manifold 50 having a rotatable actuator gear 52 which when rotated engages gear teeth on the proximal end of the sheath to retract it proximally and allow the stent to self-expand.” The Office Action continues to say, “[t]he rotation of the button 52 is about an axis coincident with the axis of the sheath.”

Turning to claim 46, which recites:

46. (Currently Amended) A distal protection assembly, comprising:
an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough;
an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;

a distal protection device disposed at the distal end of the inner shaft;

a manifold coupled to the proximal end of the inner shaft, the manifold including an actuator assembly coupled to the proximal end of the outer sheath and capable of moving the outer sheath relative to the inner sheath shaft; and

wherein the actuator assembly includes a button axially rotatable along a line that is parallel to a longitudinal axis of the outer sheath rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a gear in engagement with a number of gear teeth on the proximal end of the outer sheath.

Applicant believes that nowhere does Olson et al. appear to teach or suggest "a distal protection device disposed at the distal end of the inner shaft", as recited in claim 46. The Office Action says that Olson teaches "a distal protection device (stent)". However, Applicant must respectfully disagree. Olson et al. states, "the present invention generally relates to tubular endoluminal prostheses, such as stents, stent-grafts, and the like." (Column 1, lines 6-7). Applicant respectfully asserts that a stent, as suggested in the Office Action, or more generally, a tubular endoluminal prostheses, is not a distal protection device. In contrast, a distal protection device is a device that is placed downstream of a lesion, and the like. This is further illustrated in the present application, which recites:

During angioplasty and atherectomy procedures, stenotic debris is often separated from the stenosis and may be free to flow within the lumen of the vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural vasculature or in the lungs. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. *Because of this debris, a number of devices termed distal protection devices have been developed to filter out this debris.*

Before using a distal protection device, the device will need to be delivered to an *area downstream of where treatment will take place*. It is important that the device be delivered properly and efficiently. A need, therefore, exists for devices for delivery of distal protection devices.

After an intravascular procedure has been performed, the distal protection device will need to be removed from the vasculature. Because the distal protection devices are typically used in an expanded condition, it may be difficult to remove the device. A need, therefore exists for devices suitable for retrieval of distal protection devices. (Page 1, line 21 – page 2, line 13).

Accordingly, a stent is not a device place downstream of the treatment to filter out debris. Therefore, Applicant believes that Olson et al. does not teach “a distal protection device disposed at the distal end of the inner shaft”, as recited in claim 46. Thus, Applicant believes that claim 46 is allowable over Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependant claims 47-52, which depend from claim 46 and include significant additional limitations, are believed to be allowable over Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 53, which recites:

53. (Previously Presented) The distal protection assembly in accordance with claim 52, wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold.

After careful review of Olson et al., nowhere does Olson et al. appear to teach or suggest “wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold”, as recited in claim 53. Furthermore, nowhere has the Examiner particularly pointed out where Olson et al. teaches the claimed limitations. Applicant respectfully requests that the Examiner particularly point out where Olson et al. teaches the claimed limitations or withdraw the rejection.

Turning to claim 54, which recites:

54. (Currently Amended) A distal protection assembly, comprising:

- an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;

- an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;

- a distal protection device disposed at the distal end of the inner shaft;

- a manifold coupled to the proximal end of the inner shaft, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;

- wherein the actuator assembly includes a button axially-rotatable along a line that is parallel to a longitudinal axis of the outer sheath rotatable about an axis parallel or coincident with the axis of the outer

sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and
wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

Similar to above, nowhere does Olson et al. teach “a distal protection device disposed at the distal end of the inner shaft”, as recited in claim 54. Therefore, for at least this reason, claim 54 is believed to be allowable over Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependant claims 55-59, which depend from claim 54 and include significant additional limitations, are believed to be allowable over Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 60, which recites:

60. (Currently Amended) A distal protection assembly, comprising:

an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;

an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;

a distal protection device disposed at the distal end of the inner shaft;

a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;

wherein the actuator assembly includes a button axially-rotatable along a line that is parallel to a longitudinal axis of the outer sheath rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and

wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

Similar to above, nowhere does Olson et al. teach “a distal protection device disposed at the distal end of the inner shaft” or “a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular

member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath”, as recited in claim 54. Therefore, for at least these reasons, claim 60 is believed to be allowable over Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Claims 46-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Gilson et al. (USPN 6,669,716). After careful review, Applicant must respectfully traverse the rejection.

The Office Action recites, “Gilson discloses a device including an outer sheath 20 housing an inner shaft 2 having a section at its distal end for receiving a stent (distal protection device). The proximal end of the shaft has a manifold attached thereto which has a rotatable button 53 which when rotated about an axis parallel to the axis of the sheath causes retraction of the sheath relative to the shaft and allows the stent to self-expand.”

Turning to claim 46, which recites:

46. (Currently Amended) A distal protection assembly, comprising:
an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough;
an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;
a distal protection device disposed at the distal end of the inner shaft;
a manifold coupled to the proximal end of the inner shaft, the manifold including an actuator assembly coupled to the proximal end of the outer sheath and capable of moving the outer sheath relative to the inner sheath shaft; and
wherein the actuator assembly includes a button axially-rotatable ~~along a line that is parallel to a longitudinal axis of the outer sheath~~ rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a gear in engagement with a number of gear teeth on the proximal end of the outer sheath.

Applicant believes that nowhere does Gilson et al. appear to teach or suggest “a distal protection device disposed at the distal end of the inner shaft”, as recited in claim 46. The Office Action says that Gilson teaches “a stent (distal protection device)”. However, Applicant must respectfully disagree. Applicant respectfully asserts that a stent, as suggested in the Office Action, is not a distal protection device. In contrast, a

distal protection device is a device that is placed downstream of a lesion, and the like. This is further illustrated in the present application, which recites:

During angioplasty and atherectomy procedures, stenotic debris is often separated from the stenosis and may be free to flow within the lumen of the vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural vasculature or in the lungs. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. *Because of this debris, a number of devices termed distal protection devices have been developed to filter out this debris.*

Before using a distal protection device, the device will need to be delivered to an *area downstream of where treatment will take place*. It is important that the device be delivered properly and efficiently. A need, therefore, exists for devices for delivery of distal protection devices.

After an intravascular procedure has been performed, the distal protection device will need to be removed from the vasculature. Because the distal protection devices are typically used in an expanded condition, it may be difficult to remove the device. A need, therefore exists for devices suitable for retrieval of distal protection devices. (Page 1, line 21 – page 2, line 13).

Accordingly, a stent is not a device placed downstream of the treatment to filter out debris. Therefore, Applicant believes that Gilson et al. does not teach “a distal protection device disposed at the distal end of the inner shaft”, as recited in claim 46. Thus, Applicant believes that claim 46 is allowable over Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependent claims 47-52, which depend from claim 46 and include significant additional limitations, are believed to be allowable over Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 53, which recites:

53. (Previously Presented) The distal protection assembly in accordance with claim 52, wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold.

After careful review of Gilson et al., nowhere does Gilson et al. appear to teach or suggest “wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold”, as recited in claim 53. Furthermore, nowhere has the Examiner particularly pointed out where Gilson et al. teaches the claimed limitations. Applicant

respectfully requests that the Examiner particularly point out where Gilson et al. teaches the claimed limitations or withdraw the rejection.

Turning to claim 54, which recites:

54. (Currently Amended) A distal protection assembly, comprising:

an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;

an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;

a distal protection device disposed at the distal end of the inner shaft;

a manifold coupled to the proximal end of the inner shaft, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;

wherein the actuator assembly includes a button axially-rotatable ~~along a line that is parallel to a longitudinal axis of the outer sheath~~ rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and

wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

Similar to above, nowhere does Gilson et al. teach “a distal protection device disposed at the distal end of the inner shaft”, as recited in claim 54. Therefore, for at least this reason, claim 54 is believed to be allowable over Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependant claims 55-59, which depend from claim 54 and include significant additional limitations, are believed to be allowable over Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 60, which recites:

60. (Currently Amended) A distal protection assembly, comprising:

an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;

an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;

a distal protection device disposed at the distal end of the inner shaft;

a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;

wherein the actuator assembly includes a button axially-rotatable ~~along a line that is parallel to a longitudinal axis of the outer sheath~~ rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and

wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

Similar to above, nowhere does Gilson et al. teach “a distal protection device disposed at the distal end of the inner shaft” or “a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath”, as recited in claim 54. Therefore, for at least these reasons, claim 60 is believed to be allowable over Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 USC § 103

Claims 46-60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Turovskiy et al. (2002/0128679) in view of either Olson et al. or Gilson et al. Applicant must respectfully traverse this rejection.

The Office Action states, “Turovskiy discloses the invention as claimed including a retractable outer sheath attached to an actuator button for retracting the outer sheath relative to an inner shaft with a distal protection filter. However, the specific actuation button assembly was not disclosed. However, both Olson and Gilson disclose the same actuator button assemblies as the applicant is claiming. It would have been obvious to have used the actuators of either Olson or Gilson as these actuators avoid inadvertent linear movement of the handle to the protection device or system.”

To establish *prima facie* obviousness of a claimed invention, there must be some suggestion or motivation to modify the reference or to combine reference teachings. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). The Office Action appears to suggest that the motivation to combine Olson et al. or Gilson et al. with Turovskiy et al. is that the actuators of Olson et al. and Gilson et al. avoid inadvertent linear movement of the handle to the protection device or system. However, Applicant must respectfully disagree and believes that there is no motivation to combine Olson et al. or Gilson et al. with Turovskiy et al.

There is no motivation to modify the teachings of Turovskiy et al. to reduce the risk of inadvertent linear movement of the handle to the protection device or system because Turovskiy et al. teaches many features to prevent inadvertent movements. To further illustrate this, Turovskiy et al. recites:

[0062] Another filter/introducer apparatus adapted for use in open surgical carotid endarterectomy is depicted in FIG. 2A. Filter assembly 12 is mounted on the distal end of elongate member 11 and is operable from the proximal end of the elongate member which is attached to mechanism 5 included in filter delivery cartridge 14. The filter is collapsed and retracted into the lumen of introducer when mechanism 5 slides proximally in slot 6 as depicted in FIG. 2B. After the introducer is inserted in the artery, *filter assembly 12 is deployed by sliding mechanism 5 distally in slot 6 until it locks in groove 7, thereby fixing the filter in an open state as depicted in FIG. 2A. The distal region of introducer 15 also includes circumferentially enlarged region 19 for placement of a Javid clamp, thereby fixing the introducer within the vessel, minimizing displacement between the introducer and the vessel, and reducing trauma to the vessel. The distal region of introducer 15 is angled relative to its proximal end to facilitate insertion into an artery. Stopper 17 is sliceable mounted in the distal region of introducer 15 and can be positioned perpendicular to the longitudinal axis of the filter as depicted in FIG. 2A or parallel to the axis as depicted in FIG. 2B.*

[0063] In use, introducer 15, having filter 12 in a collapsed state, is inserted downstream atheromatous lesion 101 after arteriotomy (shown in broken line) as depicted in FIG. 2C. Filter 12 is expanded. *Stopper 17, positioned perpendicular to the longitudinal axis of the filter, minimizes displacement of the introducer and filter in the artery. Clamp 21 is placed over region 19 and endarterectomy is performed with or without a shunt.*

Alternatively, introducer 15 is inserted through an incision downstream lesion 101 prior to arteriotomy as depicted in FIG. 2D. *Stopper 17 is positioned parallel to the longitudinal axis of the filter, thereby stabilizing the introducer on the vessel.* After endarterectomy, the filter is collapsed and removed with the captured emboli generated during the procedure.

As can be seen, Turovskiy et al. teaches the use of a slot (6), a groove (7), an enlarged region (19), a Javid clamp (21), and a stopper (17) to prevent movement of the filter. Therefore, a person of skill in the art would not look to Olson et al. or Gilson et al. to prevent inadvertent movements of the device because the device of Turovskiy et al. already has features to prevent movement.

Accordingly, Applicant believes that there is no motivation to combine the teachings of Turovskiy et al. with the teachings of either Olson et al. or Gilson et al. Therefore, because there is no motivation to make the combination, a *prima facie* case of obviousness has not been made. Therefore, Applicant believes that claim 46-60 are allowable over Turovskiy et al. in view of either Olson et al. or Gilson et al.

Additionally, turning to claim 53, which recites:

53. (Previously Presented) The distal protection assembly in accordance with claim 52, wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold.

As discussed previously, nowhere does Olson et al. or Gilson et al. teach or suggest “wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold”, as recited in claim 53. Additionally, nowhere does Turovskiy et al. appear to teach or suggest “wherein the proximal tubular member includes a key adapted to engage a notch formed on the manifold” either.

Furthermore, nowhere has the Examiner specifically pointed out where Olson et al., Gilson et al., or Turovskiy et al. where they teach the claimed limitations. Applicant respectfully requests that the Examiner particularly point out where the references teach the claimed limitations or withdraw the rejection.

Therefore, because the combination of Turovskiy et al., Olson et al., and Gilson et al. do not teach all the claimed limitations, there is no *prima facie* case of obviousness. Thus, Applicant believes that claim 53 is allowable over Turovskiy et al. in view of either Olson et al. or Gilson et al. and Applicant respectfully requests withdrawal of the

rejection.

Turning to claim 60, which recites:

60. (Currently Amended) A distal protection assembly, comprising:
- an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;
 - an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;
 - a distal protection device disposed at the distal end of the inner shaft;
 - a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;
 - wherein the actuator assembly includes a button axially ~~rotatable along a line that is parallel to a longitudinal axis of the outer sheath~~ rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and
 - wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

Similar to that discussed previously, nowhere does Olson et al. or Gilson et al. teach or suggest “a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath”, as recited in claim 53. Additionally, nowhere does Turovskiy et al. appear to teach or suggest “a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath” either.

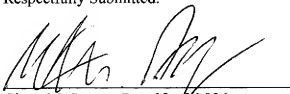
Furthermore, nowhere has the Examiner specifically pointed out where Olson et al., Gilson et al., or Turovskiy et al. where they teach the claimed limitations. Applicant respectfully requests that the Examiner particularly point out where the references teach the claimed limitations or withdraw the rejection.

Therefore, because the combination of Turovskiy et al., Olson et al., and Gilson et al. do not teach all the claimed limitations, there is no *prima facie* case of obviousness. Thus, Applicant believes that claim 60 is allowable over Turovskiy et al. in view of either Olson et al. or Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, all pending claims, namely claims 46-60, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully Submitted:

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